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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,105	09/26/2000	Maurice Moncany	2356.0062-05	5805

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	18

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/670,105	Applicant(s) MONCANY ET AL.	
	Examiner Ulrike Winkler	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27, 28, 32, 33, 38, 39, 43, 44, 49-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Amendment filed August 25, 2003 (Paper No. 17) in response to the Office Action of March 25, 2003 is acknowledged and has been entered. Claims 29-31, 34-37, 40-42, 45-48 have been cancelled. Claims 27, 28, 32, 33, 38, 39, 43, 44, 49-64 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The Office acknowledges the receipt of the new Abstract and the update to the specification listing all priority documents.

Claim Rejections - 35 USC § 112

The rejection of claims 27, 28, 32, 33, 38, 39, 43, 44 and newly added claims 49-64 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is maintained** for reason of record. The instant invention is drawn to polypeptide fragments of viral proteins, specifically viral Env proteins. The claimed polypeptides are described based on the method of obtaining the sequences of yet undiscovered and undisclosed polynucleotide sequences. Applicant's were in possession of the claimed sequences disclosed drawn to the specific viral strains disclosed in the specification HIV-1 Mal, HIV-1-Ely, HIV-1 Bru, HIV-2

Rod (CNCM No. I-522) and SIV1-lac (CNCM No. I-521). However, applicants were not in possession of yet undiscovered and mutated new viral strains as encompassed by the instant claims.

Applicant urges that it is proper to claim a compound using a product-by-process claim format. This may be true as long as the product-by-process results in the production of a single defined compound. Applicant urges that the process steps recited in the pending claims help to provide the relevant information about the structural features of the claimed polypeptides, and thus the claim provides relevant identifying characteristics. Applicant urges that the primers define the structural region of the amplified nucleic acids encoding the polypeptide.

This is not convincing, as the process cannot render obvious the claimed product. The primers define a common structural features among the group of viruses, however, it is not the primers that are being claimed in the instant inventions. The claims of the instant invention are drawn to the hypervariable region located between the primers, it is this structure that does not meet the written description requirement of the instant invention. The region in between the primers is highly diverse which indicates that the structure is different for each new undiscovered virus. The claims encompass a genus of compounds defined only by their method of obtaining the compound. The description does not provide working examples of the compounds other than those HIV-1 Mal, HIV-1-Ely, HIV-1 Bru, HIV-2 Rod (CNCM No. I-522) and SIV1-lac (CNCM No. I-521), the description teaches a method for applying PCR to discover nucleotide sequences which encode undisclosed polypeptide fragments and the person skilled in the art can understand how to use the screening method considering the common general knowledge.

> A definition by function alone "does not suffice, to sufficiently describe a coding sequence because it is only an indication of what the gene does, rather than what it is." *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998), the court affirmed a district court ruling that all of the claims of a patent were invalid because the specification did not provide an adequate written description of the rat DNA that was required by the asserted claims. The court said that "[a]n adequate written description of a DNA ... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 1 19 F.3d at 1566 (quoting *Fiers*, 984 F.2d at 1 171). "a mere wish or plan" for obtaining an invention is not enough to comply with § 1l2, ¶ 1(*Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 559, at 1566).

The claimed invention is drawn to polypeptide fragments of viral proteins, specifically viral Env proteins. The claimed polypeptides are describes based on the method of obtaining sequences of yet undiscovered and undisclosed viral strains. The specification has only proved information regarding the following viral strains HIV-1 Mal, HIV-1-Ely, HIV-1 Bru, HIV-2 Rod (CNCM No. I-522) and SIV1-lac (CNCM No. I-521). However, no structural information is provided regarding any other viral polypeptides, nor is there any indication that the artisan actually implemented the method of the claims to identify such polypeptides. This situation is analogous to that of *Regents of the University of California v Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention. The claim fails to comply with the written description requirement.

The rejection of claims 27, 28, 32, 33, 38, 39, 43, 44 and newly added claims 49-64 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which

it is most nearly connected, to make and/or use the invention **is maintained** for reason of record. The instant invention is drawn to polypeptide fragments of viral proteins, specifically viral Env proteins. The specific strains of viruses disclosed in the specification are HIV-1 Mal, HIV-1-Ely, HIV-1 Bru, HIV-2 Rod (CNCM No. I-522) and SIV1-lac (CNCM No. I-521). The claimed polypeptides are describes based on the method of obtaining the sequences of yet undiscovered and undisclosed polypeptides.

Applicant urges that the office has not provided any technical reasons for questioning why one of ordinary skill in the art could not make the claimed polypeptide using the process steps recited in the pending claims.

A patent specification that provides only a starting point or direction for further research is not enabling because it does not provide full and clear terms that teach others how to make and use an invention that will be discovered sometime in the future.

> It must be remembered, however, that"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute an enabling disclosure." *Genentech. Inc.* v. *Novo Nordisk A/S,* 108 F83d 1361, 1365 (Fed. Cir.), cert denied, 522 U.S. 963 (1997)

The instant fact pattern fails to disclose a particular structure for the claimed polypeptide sequence of viral strains that are not disclosed in the instant specification, as the PCR method amplifies those regions belonging to the "hypervariable region" (the regions with the greatest diversity of mutations) of the Env protein. The specification provides a method of screening for nucleotide sequences that encode proteins, however, the specification does not disclose the structure of the proteins belonging to viral strains and mutants other than those five (HIV-1 Mal, HIV-1-Ely, HIV-1 Bru, HIV-2 Rod (CNCM No. I-522) and SIV1-lac (CNCM No. I-521))

disclosed in the specification without undue experimentation. Furthermore an assay for finding a product is not equivalent to a positive recitation of how to make such a product. This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112 first paragraph. Therefore, the instant invention is not enabled for the peptide fragments and the pharmaceutical compositions comprising the peptide fragments.

New Rejection:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 28, 32, 33, 38, 39, 43, 44 and 49-64 recite limitations in the claims that have insufficient antecedent basis for the limitation in the claims. For example: the "a nucleotide sequence" followed by the limitation "the nucleic acid". The claims make reference to "said first primer" and "said second primer" without disclosing that there is a first or second primer to begin with. The claim makes reference to a region of "said nucleic acid genome", yet the claim only makes reference to "a viral genome". The claims makes reference to "said complementary strands" yet the claim only makes reference to a single strand before. The claims are replete of inconsistencies Applicant is advised to make all correction necessary to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 11/17/03